IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

GENETICS & IVF INSTITUTE,

Plaintiff,

vs.

DAVID KAPPOS, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office; UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants.

Civ. Action No.: 1:10cv996 (AJT/TRJ)

COMPLAINT

Plaintiff Genetics & IVF Institute ("GIVF") brings this action against Defendants United States Patent and Trademark Office ("USPTO") and David Kappos, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and hereby alleges as follows:

NATURE OF ACTION

1. This is a civil action under the Administrative Procedure Act, 5 U.S.C. §§ 551-706, seeking to set aside the denial of an application pursuant to the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, to extend the term of U.S. Patent No. 5,135,759 ("the '759 patent"), which is a pharmaceutical patent owned by the United States Department of Agriculture ("USDA"), and exclusively licensed to GIVF.

PARTIES

2. Plaintiff GIVF is a Virginia corporation headquartered in Fairfax, Virginia that is the exclusive licensee under the '759 patent.

3. Defendant USPTO is a federal agency within the United States Department of Commerce. The USPTO is headquartered in Alexandria, Virginia.

4. Defendant David Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the USPTO. Mr. Kappos is sued in his official capacity as Director.

JURISDICTION & VENUE

5. This action arises under the following sections of the United States Code: 5 U.S.C. §§ 702 and 704, and 35 U.S.C. § 156.

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361.

7. Plaintiff challenges Defendant's denial of the USDA's application for an interim term extension for the '759 patent. Plaintiff was directly aggrieved by this final agency action.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)(1) or (b)(2), because Defendants reside in this district and perform their official duties here, including any enforcement of the statute challenged in this action.

9. Venue also is proper in this Division pursuant to Local Civ. R. 3(C) because Defendants reside in the Alexandria Division.

LEGAL BACKGROUND

10. The Hatch-Waxman Act prescribes that, if the patent owner or its agent "reasonably expects that the applicable regulatory review period [for the patent] may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an

application to the Director for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire." 35 U.S.C. § 156(d)(5)(A). If the Director determines that the patent would be eligible for extension of the patent term, but for the regulatory review of the patent for market use, then the Director may grant an interim extension for that patent for a period of not more than 1 year. *Id.* § 156(d)(5)(B).

11. After an initial interim extension has been granted, the patent holder or its agent may apply for up to 4 subsequent interim extensions, provided that each subsequent application for interim extension of the patent is made "during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension." *Id.* § 156(d)(5)(C).

12. Under 35 U.S.C. § 156(d)(5), the patent owner or its agent therefore is entitled to extend its patent beyond the expiration of the patent term as long as it is awaiting regulatory approval from the United States Food and Drug Administration ("FDA") and satisfies other statutory criteria. 35 U.S.C. § 156(d)(5).

FACTUAL BACKGROUND

13. The '759 patent is assigned to the USDA and was issued on August 4, 1992.

14. The original expiration date of the '759 patent was August 4, 2009.

15. USDA has exclusively licensed the '759 patent, in a particular field of use, to GIVF.

16. As the exclusive licensee of the '759 patent, GIVF has the sole worldwide right to make, use, sell, lease, or otherwise dispose of products under the patent. GIVF also was granted rights to bring actions against third-parties to enforce the exclusivity of the products set forth under the patent.

17. On April 24, 2000, consistent with its obligations under the license, GIVF filed an Investigational Device Exemption with the FDA for use of the '759 patent.

18. FDA review of GIVF's product under the '759 patent still was ongoing in February 2009, six months prior to the original expiration of the '759 patent.

19. On June 8, 2009, on behalf of the USDA, GIVF filed with the USPTO a request for an interim patent term extension for the '759 patent. The USPTO granted the extension on July 28, 2009, extending the term of the '759 patent for one year from the original patent term expiration date, *i.e.*, until August 4, 2010. Grant of interim extension of the term of U.S. Patent No. 5,135,759, 74 Fed. Reg. 38585 (Aug. 4, 2009).

20. Under § 156(d)(5)(C), the period for filing the second interim patent term extension for the '759 patent began on June 5, 2010 and ended on July 6, 2010. July 5 was a federal holiday.

21. On July 27, 2010, after discussions with attorneys at the USPTO, GIVF filed on behalf of the USDA a petition under 37 C.F.R. §§ 1.182 and 1.183 for an extension of time to file an application for a second interim patent term extension for the '759 patent.

22. The petition argued that the USPTO has discretion to authorize the USDA's request for a second interim patent term extension, notwithstanding the fact that it was filed beyond the statutorily prescribed deadline of 30 days prior to the expiration of the previous interim extension.

23. The petition further explained that, with the exception of mild tardiness, the application for a second interim patent term extension satisfies all of the statutory criteria for the grant of an extension under 35 U.S.C. § 156. Indeed, the USPTO found all of the relevant factors present in 2009. 74 Fed. Reg. 38585. In addition, the USDA—through its licensee,

GIVF—has diligently sought commercial approval for its patented product from the FDA. This is not a case, therefore, where the USDA or its licensee somehow sat on its rights before the FDA.

24. On August 2, 2010, the USPTO issued a final decision denying the USDA's request for an extension of time to file a second interim patent term extension. The USPTO designated this decision final agency action for purposes of judicial review under the Administrative Procedure Act. In its decision, the USPTO concluded, among other things, that it did not have discretion to issue a second interim patent term extension under 35 U.S.C. § 156(d)(5)(C) for the '759 patent without a timely filed application.

ADMINISTRATIVE PROCEDURE ACT CLAIM

25. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

26. Under the Administrative Procedure Act, "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review." 5 U.S.C. § 704. "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

27. In this action, Plaintiff, as the exclusive licensee of the '759 patent, challenges the USPTO's denial of the USDA's application to extend the term of the patent covering the '759 patent.

28. The USPTO's denial of the USDA's application for a second interim patent term extension already has inflicted enormous harm on Plaintiff by causing the '759 patent to expire, even though it still is being actively reviewed by the FDA.

29. The expiration of the '759 patent has, in turn, caused the expiration of Plaintiff's exclusive licensee rights under the license agreement reached between Plaintiff and the USDA. Plaintiff accordingly has lost its past, present, and future rights to exclusively make, use, sell, lease, or otherwise dispose of products under the '759 patent. Plaintiff also has lost its ability to prevent third parties from making, using, selling, leasing, or otherwise disposing of products set forth under the patent, or from seeking FDA approval for such products under the patent.

30. The language, structure, and purpose of § 156 give the USPTO discretion to authorize a second interim patent term extension sought outside of the statutory window. Though § 156 states that "[t]he term of a patent . . . *shall* be extended" as long as certain criteria are met, 35 U.S.C. § 156(a) (emphasis added), the regulations promulgated pursuant to this statute do not use the word "shall." Instead, they list the same statutory criteria, and state that the "[t]he term of a patent *may* be extended." 37 C.F.R. § 1.720 (emphasis added). Indeed, this Court recently recognized in a similar matter that "[t]here is a strong presumption that when Congress repeats the same word in the same statute, it intends for that word to be given the same meaning." *The Medicines Company v. Kappos*, 699 F. Supp. 2d 804, 809 (E.D. Va. Mar. 16, 2010) ("*Medicines I*"). If the word "shall" in § 156(a) means "may" as the USPTO seems to indicate in its own regulations, then that word should have the same meaning in § 156(d)(5)(C) as well. Given the permissive, discretionary nature of the word "shall" in § 156, it stands to reason that the USPTO has the discretion to approve the USDA's petition for a second interim patent term extension.

31. The time period set forth in § 156(d)(5)(C) is not essential to § 156. In deciding whether a statutory provision is mandatory, many courts ask whether the "requirement is so essential a part of the plan that the legislative intent would be frustrated by noncompliance."

Vaughan v. Winston, 83 F.2d 870, 872 (10th Cir. 1936). In those instances where the "requirement is a detail of procedure which does not go to the substance of the thing done," it is merely "directory" and not "mandatory." *Id.* In this case, § 156(d)(5)(C)'s time-window is nothing more than "a detail of procedure," having nothing to do with the substance of the right at issue—the extension of the patent during a period of regulatory review. In this case, the USDA satisfies all of the criteria for an extension, and it filed its application during a time when its patent was still in effect. Under such circumstances, the time window under § 156(d)(5)(C) is simply a matter of procedure, not substance.

32. This conclusion is further confirmed by the remedial nature of the Hatch-Waxman Act, which was created in order to "compensate for the delay in obtaining FDA approval," *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996). This Court recently held in *The Medicines Company* that "[a]ll of the provisions of a remedial statute [such as § 156] . . . should be construed liberally." *The Medicines Co. v. Kappos*, __ F. Supp. 2d __, 2010 WL 3063617, at *8 (E.D. Va. Aug. 3, 2010) ("*Medicines II*"). This Court then went on to state that "courts have broadly construed timing provisions in remedial statutes [because] 'a generous reading, in favor of those whom Congress intended to benefit from the law, is also appropriate when considering issues of time limits and deadlines.'" *Id.* (quoting *Kelley v. Alamo*, 964 F.2d 747, 750 (8th Cir. 1992)).

33. By letting this patent expire, the USPTO will undermine the congressional intent to not prejudice patent owners while the regulatory process works. In contrast, granting the patent extension will impose no harm on the public at all. At the time the USDA sought its second interim patent term extension, the public was on notice of the existence of the '759 patent and, thus, would not have been harmed by an extension of that patent in accordance with the

statute. Under such circumstances, the "shall" language in § 156(d)(5)(C) should not prevent the USPTO from having granted USDA's second interim patent term extension request.

34. Consistent with the remedial nature of the statute, 37 C.F.R. § 1.183 grants the USPTO discretion to permit a late filing, when not barred by statute, "[i]n an extraordinary case, when justice requires." The USPTO also is empowered by regulation to address "[a]ll situations not specifically provided for in the regulations . . . in accordance with the merits of each situation." 37 C.F.R. § 1.182. Here, 37 C.F.R. § 1.790(a) implements the requirements for obtaining an interim extension of patent term under 35 U.S.C. § 156(d)(5), providing that such an extension must be filed "during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension." 37 C.F.R. § 1.790(a). Accordingly, sections 1.182 and 1.183 of the regulations provide the USPTO with ample discretion to remedy the USDA's petition by setting aside the requirements set forth in 37 C.F.R. § 1.790(a).

35. The USPTO's decision reflects a misapprehension of agency authority under 35 U.S.C. § 156. The decision also misinterprets agency regulations and case law because it undermines the remedial design of the patent term restoration system. The decision further ignores this Court's recent opinions in *The Medicines Company* case, in which this Court definitively held that all provisions of a remedial statute, in particular those involving timing, should be construed liberally. *See generally Medicines I*, 699 F. Supp. 2d 804 (E.D. Va. Mar. 16, 2010); *Medicines II*, 2010 WL 3063617 (E.D. Va. Aug. 3, 2010).

36. There is no dispute that, but for the issue of the application's timeliness, the substantive requirements of the Hatch-Waxman Act have been met, and the '759 patent is entitled to an extension. For the reasons stated herein, the USPTO's decision that it lacks discretion to approve the USDA's petition for a second interim patent term extension should be

set aside. The matter should be remanded to the USPTO with instructions that the USPTO possesses such discretion and to exercise that discretion in reviewing the patent term extension application for the '759 patent.

37. Accordingly, this decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court:

A. Vacate and set aside the USPTO's August 2, 2010, decision denying the USDA's application of the interim extension of the term for U.S. Patent No. 5,135,759;

B. Declare that the USPTO has the discretion to extend the term of U.S. Patent No. 5,135,759 for the full period required under 35 U.S.C. § 156;

C. Remand the case to the USPTO for determination of the patent term extension application for the '759 patent in light of the fact that the USPTO possesses discretion to extend a patent term under § 156.

D. Order that, pending the USPTO's resolution on remand of the patent term extension application for the '759 patent, the exclusive license held by GIVF for the '759 patent remain in effect.

E. Award Plaintiff its costs and reasonable attorney's fees as appropriate; and

F. Grant such further and other relief as this Court deems just and proper.

Respectfully submitted,

Dated: September 1, 2010

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